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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,825	09/07/99	FRIESEN	D PC9835AJTJ

EXAMINER	
KULKOSKY, P	
ART UNIT	**PAPER NUMBER**
1615	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/380,825	Dwayne T. Friesen et al
Examiner	**Group Art Unit**
P. Kulkosky	1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 - 29 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 - 29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 ☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0,415,612 or Ranade 4,803,076 or Bacopoulos each taken alone or in view of Thakkar et al. 4,847,092.

The composition of the instant claims is obvious, prima facie, since it contains solubilizers known to the art (see EPA '612, page 3; Ranade et al., examples 4, 5). It is clear that it is standard in the art to combine gelucire and cellulose in sustained release formulations (see Thakkar et al.). It would be routine to choose solubilizers such as those of claim 14 as matrixes for setraline as same are used in EPA 612 (PEG) and are of the same class of matrix materials as Gelucire. If the release effects obtained in the specific examples of the example are improved, it would be necessary to demonstrate why the references teach against or would not support combination of solubilizing agents as used in Table 1 (page 9, specification). Motivation to use a particular "solubilizing agent" with setraline HCL would be present in the known properties of the advertized commercially available "solubilizers". A composition containing setraline with solubilizer would be obvious on the basis of the properties the known solubilizer would contribute to any composition, regardless of other excipients and release agents. The use of any other release agent in a composition of the instant claims would be obvious, but the achievement

of a certain release rate under chloride environment conditions would be routinely achievable by adjustment of the ratio of materials in a given release matrix. Thus, the claims do not specify compositions whose release rates are due to use of solubilizing agent alone.

Claims 1-29 are rejected under 35 U.S.C. 112, par. 2.

The compositions of the instant claims are not defined by ranges of amounts of the critical components which are disclosed which are disclosed as necessary to achieve the improved solubilization effect of setraline in chloride ion containing solution.

The "comparative" composition of claims 15, 16 is not clearly comprised of definite components.

The terms "immediate release dosage from" and "controlled release dosage form" are not descriptive of rates or forms limited sufficiently to indicate a reasonable scope of same to those skilled in the art. The term "use environment containing chloride ions" is vague and does not describe conditions which can be set up for testing by those skilled in the art.

The physical properties of the dosage form of claim 1 are open to any description, whereas the tablets of the specification are the "composition" disclosed as the invention.

The "compositions of matter" are not described in terms which indicate the utility of same (to treat a condition or disease).

The term "solubilizing agent" does not define chemical compounds (such as those of claim 7) which are disclosed as useful.

The method of claim 23 is not limited to "solubilizing agents" capable of yielding compositions having the effective comparative properties.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 are rejected under Judicial policy as constitutive of double patenting in views of claims of copending S.N. 09/380977 and S.N. 09/380825 or S.N. 09/380900.

The composition of the claims of the cited applications are comprised of the same ingredients and are not distinguishable from one another. The use of excipients, matrix modifiers, etc. to adjust release properties would be obvious to those skilled in the art.

References (U) and (V) are cited of interest.

Any inquiry concerning this communication should be directed to Peter Kulkosky at telephone number (703) 308-2380.

P. Kulkosky:jmr

November 17, 2000

PETER F. KULKOSKY
PRIMARY EXAMINER